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cient for which a lens moves on the eye is 0.27×10^{-6} cm²/sec. The highest value of Hydrodell Water Permeability Coefficient for a lens which binds on the eye is 0.08×10^{-6} cm²/sec. Thus, a contact lens preferably has a Hydrodell Water Permeability Coefficient greater than about 0.08×10^{-6} cm²/sec., more preferably greater than 0.27×10^{-6} cm²/sec.

The invention has been described in detail, with reference to certain preferred embodiments, in order to enable the reader to practice the invention without undue experimentation. Theories of operation have been offered to better enable the reader to understand the invention, but such theories do not limit the scope of the invention. In addition, a person having ordinary skill in the art will readily recognize that many of the previous components, compositions, and parameters may be varied or modified to a reasonable extent without departing from the scope and spirit of the invention.

Furthermore, titles, headings, example materials or the like are provided to enhance the reader's comprehension of this document, and should not be read as limiting the scope of the present invention. Accordingly, the intellectual property rights to the invention are defined by the following claims, reasonable extensions and equivalents thereof, as interpreted in view of the disclosure herein.

That which is claimed is:

1. An ophthalmic lens having ophthalmically compatible inner and outer surfaces, said lens being suited to extended periods of wear in continuous, intimate contact with ocular tissue and ocular fluids, said lens comprising a polymeric material which has a high oxygen permeability and a high ion permeability, said polymeric material being formed from polymerizable materials comprising:

- (a) at least one oxyperm polymerizable material and
- (b) at least one ionoperm polymerizable material,

wherein said lens allows oxygen permeation in an amount sufficient to maintain corneal health and wearer comfort during a period of extended, continuous contact with ocular tissue and ocular fluids,

wherein said oxyperm polymerizable material forms a phase or phases substantially separate from the phase or phases formed by said ionoperm polymerizable material,

wherein said lens allows ion or water permeation via ion or water pathways in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during a period of extended, continuous contact with ocular tissue and ocular fluids,

wherein said ionoperm polymerizable material, if polymerized alone would form a hydrophilic polymer having a water content of at least 10 weight percent upon full hydration, and

wherein said ophthalmic lens has an oxygen transmissibility of at least about 70 barrers/mm and an ion permeability characterized either by (1) an Ionoton Ion Permeability Coefficient of greater than about 0.2×10^{-6} cm²/sec, or (2) an Ionoflux Diffusion Coefficient of greater than about 1.5×10^{31} mm²/min, wherein said ion permeability is measured with respect to sodium ions.

2. An ophthalmic lens of claim 1, wherein said ophthalmic lens is selected from the group consisting of contact lenses for vision correction, contact lenses for eye color modification, ophthalmic drug delivery devices, and ophthalmic wound healing devices.

3. An ophthalmic lens of claim 2, wherein said ophthalmic lens is a contact lens.

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4. An ophthalmic lens of claim 1, wherein said ophthalmic lens has an oxygen transmissibility of at least about 75 barrers/mm.

5. An ophthalmic lens of claim 4, wherein said ophthalmic lens has an oxygen transmissibility of at least about 87 barrers/mm.

6. An ophthalmic lens of claim 1, wherein said polymeric material comprises an ionoperm phase which extends continuously from the inner surface of the ophthalmic lens to the outer surface of the ophthalmic lens.

7. An ophthalmic lens of claim 1, wherein said polymeric material comprises an oxyperm phase which extends continuously from the inner surface of the ophthalmic lens to the outer surface of the ophthalmic lens.

8. An ophthalmic lens of claim 1, wherein said polymeric material comprises a plurality of co-continuous phases, including at least one oxyperm phase which extends continuously from the inner surface of the ophthalmic lens to the outer surface of the ophthalmic lens and at least one ionoperm phase which extends continuously from the inner surface of the ophthalmic lens to the outer surface of the ophthalmic lens.

9. An ophthalmic lens of claim 1, wherein said polymeric material comprises at least one ion or water pathway which extends continuously from the inner surface of the ophthalmic lens to the outer surface of the ophthalmic lens.

10. An ophthalmic lens of claim 1, wherein said polymeric material comprises at least one oxygen pathway which extends continuously from the inner surface of the ophthalmic lens to the outer surface of the ophthalmic lens.

11. An ophthalmic lens of claim 1, wherein said polymeric material comprises a plurality of co-continuous pathways, at least one being an ion or water pathway and at least one other being an oxygen pathway, which pathways extend continuously from the inner surface of the lens to the outer surface of the lens.

12. An ophthalmic lens of claim 11, wherein said co-continuous pathways include a continuous phase of ionoperm polymeric material and a continuous phase of siloxane-containing polymeric material.

13. An ophthalmic lens of claim 11, wherein said pathways have a domain size which is less than a size which undesirably distorts visible light in an amount which is visible to the eye of the wearer.

14. An ophthalmic lens of claim 1, wherein said lens has an Ionoton Ion Permeability Coefficient of greater than about 0.3×10^{-6} cm²/sec and wherein said Ionoton Ion Permeability Coefficient is measured with respect to sodium ions.

15. An ophthalmic lens of claim 14, wherein said lens has an Ionoton Ion Permeability Coefficient of greater than about 0.4×10^{-6} cm²/sec and wherein said Ionoton Ion Permeability Coefficient is measured with respect to sodium ions.

16. An ophthalmic lens of claim 1, wherein said lens has an Ionoflux Diffusion Coefficient of greater than about 2.6×10^{-6} mm²/min and wherein said Ionoflux Ion Permeability Coefficient is measured with respect to sodium ions.

17. An ophthalmic lens of claim 16, wherein said lens has an Ionoflux Diffusion Coefficient of greater than about 6.4×10^{-6} mm²/min and wherein said Ionoflux Ion Permeability Coefficient is measured with respect to sodium ions.

18. An ophthalmic lens of claim 1, wherein said lens has a Hydrodell Water Permeability Coefficient of greater than about 0.2×10^{-6} cm²/sec.

19. An ophthalmic lens of claim 18, wherein said lens has a Hydrodell Water Permeability Coefficient of greater than about 0.3×10^{-6} cm²/sec.

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20. An ophthalmic lens of claim 19, wherein said lens has a Hydrodell Water Permeability Coefficient of greater than about 0.4×10^{-6} cm²/sec.

21. An ophthalmic lens of claim 1, wherein when hydrated, said lens has an equilibrium water content of less than about 32 weight percent when tested in accordance with the Bulk Technique.

22. An ophthalmic lens of claim 21, wherein when hydrated, said lens has an equilibrium water content of about 10 to about 30 weight percent when tested in accordance with the Bulk Technique.

23. An ophthalmic lens of claim 22, wherein when hydrated, said lens has an equilibrium water content of about 15 to about 25 weight percent when tested in accordance with the Bulk Technique.

24. An ophthalmic lens of claim 1, wherein said polymeric material is formed from a polymerizable mixture comprising:

- (a) about 60 to about 85 weight percent oxypem macromer; and
- (b) about 15 to about 40 weight percent ionopem monomer.

25. An ophthalmic lens of claim 24, wherein said polymeric material is formed from a polymerizable mixture comprising:

- (a) about 70 to about 82 weight percent oxypem macromer; and
- (b) about 18 to about 30 weight percent ionopem monomer.

26. An ophthalmic lens of claim 1, wherein said lens allows oxygen transmission in an amount sufficient to prevent any clinically significant corneal swelling during a period of extended, continuous contact with ocular tissue and ocular fluids.

27. An ophthalmic lens of claim 1, wherein said lens produces, after wear of about 24 hours, including normal sleep periods, less than about 8% corneal swelling.

28. An ophthalmic lens of claim 27, wherein said lens produces, after wear of about 24 hours, including normal sleep periods, less than about 6% corneal swelling.

29. An ophthalmic lens of claim 28, wherein said lens produces, after wear of about 24 hours, including normal sleep periods, less than about 4% corneal swelling.

30. An ophthalmic lens of claim 1, wherein said period of extended continuous contact is at least 24 hours.

31. An ophthalmic lens of claim 30, wherein said period of extended continuous contact is at least 4 days.

32. An ophthalmic lens of claim 31, wherein said period of extended continuous contact is at least 7 days.

33. An ophthalmic lens of claim 32, wherein said period of extended continuous contact is at least 14 days.

34. An ophthalmic lens of claim 33, wherein said period of extended continuous contact is at least 30 days.

35. An ophthalmic lens of claim 1, wherein said lens has a tensile modulus of 3 MPa or less.

36. An ophthalmic lens of claim 1, wherein said lens has a short relaxation time constant of greater than about 3.5 seconds, wherein said short relaxation time constant is measured in phosphate-buffered saline solution.

37. An ophthalmic lens of claim 26, wherein said lens has an Ionoton Ion Permeability Coefficient, P, of greater than about 0.2×10^{-6} cm²/sec, wherein said short relaxation time constant is measured in phosphate-buffered saline solution and wherein said Ionoton Ion Permeability Coefficient is measured with respect to sodium ions.

38. An ophthalmic lens of claim 26, wherein said lens has an Ionoflux Diffusion Coefficient of greater than about

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2.6×10^{-6} mm²/min, wherein said short relaxation time constant is measured in phosphate-buffered saline solution and wherein said Ionoton Ion Permeability Coefficient is measured with respect to sodium ions.

39. An ophthalmic lens of claim 36, wherein said lens has a Hydrodell Water Permeability Coefficient of greater than about 0.2×10^{-6} cm²/min, wherein said short relaxation time constant is measured in phosphate-buffered saline solution.

40. An ophthalmic lens of claim 1, wherein the polymeric material has a tan δ above about 0.25 at about 10 Hz, wherein said short relaxation time constant is measured in phosphate-buffered saline solution.

41. An ophthalmic lens of claim 1, wherein said lens has an Ionoton Ion Permeability Coefficient of greater than about 0.3×10^{-6} cm²/sec, a tensile modulus of 3 MPa or less, and a short relaxation time constant of greater than about 3.5 seconds, wherein said short relaxation time constant is measured in phosphate-buffered saline solution and wherein said Ionoton Ion Permeability Coefficient is measured with respect to sodium ions.

42. An ophthalmic lens of claim 1, wherein said lens has an Ionoflux Diffusion Coefficient of greater than about 2.6×10^{-6} mm²/min., a tensile modulus of 3 MPa or less, and a short relaxation time constant of greater than about 3.5 seconds, wherein said short relaxation time constant is measured in phosphate-buffered saline solution and wherein said Ionoflux Ion Permeability Coefficient is measured with respect to sodium ions.

43. An ophthalmic lens of claim 1, wherein said lens has a Hydrodell Water Permeability Coefficient of greater than about 0.3×10^{-6} cm²/min., a tensile modulus of 3 MPa or less, and a short relaxation time constant of greater than about 3.5 seconds, wherein said short relaxation time constant is measured in phosphate-buffered saline solution.

44. An ophthalmic lens having ophthalmically compatible inner and outer surfaces, said lens being suited to extended periods of wear in continuous, intimate contact with ocular tissue and ocular fluids, said lens comprising a polymeric material which has a high oxygen permeability and a high ion permeability, said polymeric material being formed from polymerizable materials comprising at least one polymerizable material comprising:

- (a) at least one oxypem segment; and
- (b) at least one ionopem segment,

wherein said lens allows oxygen permeation in an amount sufficient to maintain corneal health and wearer comfort during a period of extended, continuous contact with ocular tissue and ocular fluids,

wherein said oxypem polymerizable material forms a phase or phases substantially separate from the phase of phase formed by said ionopem polymerizable material,

wherein said lens allows ion or water permeation via ion or water pathways in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during a period of extended, continuous contact with ocular tissue and ocular fluids,

Wherein said ionopem polymerizable material, if polymerized alone, would form a hydrophilic polymer having a water content of at least 10 weight percent upon full hydration, and

Wherein said ophthalmic lens has an oxygen transmissibility of at least about 70 barrers/mm and an ion permeability characterized either by (1) an Ionoton Ion Permeability Coefficient of greater than about 0.2×10^{-6}

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6 cm²/sec. or (2) an Ionoflux Diffusion Coefficient of greater than about 1.5×10⁻⁶ mm²/min. Wherein said ion permeability is measured with respect to sodium ions.

45. An ophthalmic lens of claim 44, wherein said ophthalmic lens has an oxygen transmissibility of at least about 75 barrers/mm.

46. An ophthalmic lens of claim 45, wherein said ophthalmic lens has an oxygen transmissibility of at least about 87 barrers/mm.

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47. An ophthalmic lens of claim 44, wherein said lens has an Ionoflux Diffusion Coefficient of greater than about 1.5×10⁻⁶ mm²/min and wherein said Ionoflux Ion Permeability Coefficient is measured with respect to sodium ions.

48. An ophthalmic lens of claim 44, wherein said lens has a Hydrocell Water Permeability Coefficient of greater than about 0.2×10⁻⁶ cm²/sec.

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[54] EXTENDED WEAR OPHTHALMIC LENS

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[58] Field of Search 523/106, 107;
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[57] ABSTRACT

An ophthalmic lens suited for extended-wear for periods of at least one day on the eye without a clinically significant amount of corneal swelling and without substantial wearer discomfort. The lens has a balance of oxygen permeability and ion or water permeability, with the ion or water permeability being sufficient to provide good on-eye movement, such that a good tear exchange occurs between the lens and the eye. A preferred lens is a copolymerization product of a oxyperm macromer and an ionoperm monomer. The invention encompasses extended wear contact lenses, which include a core having oxygen transmission and ion transmission pathways extending from the inner surface to the outer surface.

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REEXAMINATION CERTIFICATE ISSUED UNDER 35 U.S.C. 307

THE PATENT IS HEREBY AMENDED AS
INDICATED BELOW.

Matter enclosed in heavy brackets [] appeared in the patent, but has been deleted and is no longer a part of the patent; matter printed in italics indicates additions made to the patent.

ONLY THOSE PARAGRAPHS OF THE
SPECIFICATION AFFECTED BY AMENDMENT
ARE PRINTED HEREIN.

Column 11, lines 42–50:

An Ionoflux Diffusion Coefficient of greater than about $[6.4 \times 10^{-6}]$ 1.5×10^{-6} mm²/min is preferred for achieving sufficient on-eye movement. More preferably, the Ionoflux Diffusion Coefficient is greater than about 2.6×10^{-6} mm²/min, while most preferably, the Ionoflux Diffusion Coefficient is greater than about $[1.5 \times 10^{-6}]$ 6.4×10^{-6} mm²/min. It must be emphasized that the Ionoflux Diffusion Coefficient correlates with ion permeability through the lens, and thereby is a predictor of on-eye movement.

AS A RESULT OF REEXAMINATION, IT HAS BEEN
DETERMINED THAT:

Claim 30 is cancelled.

Claims 1, 31 and 44 are determined to be patentable as amended.

Claims 2–29, 32–43 and 45–48, dependent on an amended claim, are determined to be patentable. New claims 49–64 are added and determined to be patentable.

1. An ophthalmic lens having *a surface modified by a surface treatment process, said lens having* ophthalmically compatible inner and outer surfaces, said lens being suited to extended periods of wear in continuous, intimate contact with ocular tissue and ocular fluids *while having adequate movement on the eye with blinking to promote adequate tear exchange and without producing significant corneal swelling, without having substantial amounts of lipid adsorption, and without causing substantial wearer discomfort during a period of wear of at least 24 hours*, said lens comprising a polymeric material which has a high oxygen permeability and a high ion permeability, said polymeric material being formed from polymerizable materials comprising:

- (a) at least one oxyporm polymerizable material and
- (b) at least one ionoporm polymerizable material,

wherein said lens allows oxygen permeation in an amount sufficient to maintain corneal health and wearer comfort during [a] the period of extended, continuous contact with ocular tissue and ocular fluids,

wherein said oxyporm polymerizable material forms a phase or phases substantially separate from the phase or phases formed by said ionoporm polymerizable material,

wherein said lens allows ion or water permeation via ion or water pathways in an amount sufficient to enable the lens to move on the eye such that corneal health is not

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substantially harmed and wearer comfort is acceptable during [a] the period of extended, continuous contact with ocular tissue and ocular fluids,

wherein said ionoporm polymerizable material, if polymerized alone would form a hydrophilic polymer having a water content of at least 10 weight percent upon full hydration, and

wherein said ophthalmic lens has an oxygen transmissibility of at least about 70 barrers/mm and an ion permeability characterized either by (1) an Ionoton Ion Permeability Coefficient of greater than about 0.2×10^{-6} cm²/sec[.] or (2) an Ionoflux Diffusion Coefficient of greater than about 1.5×10^{-6} mm²/min. wherein said ion permeability is measured with respect to sodium ions.

31. An ophthalmic lens of claim [30] 1, wherein said period of extended continuous contact is at least 4 days.

44. An ophthalmic lens having *a surface modified by a surface treatment process, said lens having* ophthalmically compatible inner and outer surfaces, said lens being suited to extended periods of wear in continuous, intimate contact with ocular tissue and ocular fluids *while having adequate movement on the eye with blinking to promote adequate tear exchange and without producing significant corneal swelling, without having substantial amounts of lipid adsorption, and without causing substantial wearer discomfort during a period of wear of at least 24 hours*, said lens comprising a polymeric material which has a high oxygen permeability and a high ion permeability, said polymeric material being formed from polymerizable materials comprising at least one polymerizable material comprising:

- (a) at least one oxyporm segment; and
- (b) at least one ionoporm segment,

wherein said lens allows oxygen permeation in an amount sufficient to maintain corneal health and wearer comfort during [a] the period of extended, continuous contact with ocular tissue and ocular fluids,

wherein said oxyporm segment forms a phase or phases substantially separate from the phase [of phase] or phases formed by said ionoporm segment,

wherein said lens allows ion or water permeation via ion or water pathways in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during [a] the period of extended, continuous contact with ocular tissue and ocular fluids,

[Wherein] wherein said ionoporm segment, if polymerized alone, would form a hydrophilic polymer having a water content of at least 10 weight percent upon full hydration, and

[Wherein] wherein said ophthalmic lens has an oxygen transmissibility of at least about 70 barrers/mm and an ion permeability characterized either by (1) an Ionoton Ion Permeability Coefficient of greater than about 0.2×10^{-6} cm²/sec[.] or (2) an Ionoflux Diffusion Coefficient of greater than about 1.5×10^{-6} mm²/min, [Wherein] wherein said ion permeability is measured with respect to sodium ions.

49. An ophthalmic lens comprising a core material surrounded, at least in part, by a surface modified by a surface treatment process, said lens having ophthalmically compatible inner and outer surfaces which are more hydrophilic and lipophobic than the core material, said lens being suited to extended periods of wear in continuous, intimate contact with ocular tissue and ocular fluids while providing adequate movement on the eye with blinking to promote adequate tear exchange and without producing significant

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corneal swelling, without having substantial amounts of lipid adsorption, and without causing substantial wearer discomfort during a period of wear at least 24 hours, said lens comprising a polymeric material which has a high oxygen permeability and a high ion permeability, said polymeric material being formed from polymerizable materials comprising:

- (a) at least one oxyperm polymerizable material and
- (b) at least one ionoperm polymerizable material,

wherein said lens allows oxygen permeation in an amount sufficient to maintain corneal health and wearer comfort during the period of extended, continuous contact with ocular tissue and ocular fluids,

wherein said oxyperm polymerizable material forms a phase of phases substantially separate from the phase or phases formed by said ionoperm polymerizable material,

wherein said lens allows ion or water permeation via ion or water pathways in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during the period of extended, continuous contact with ocular tissue and ocular fluids,

wherein said ionoperm polymerizable material, if polymerized alone would form a hydrophilic polymer having a water content of at least 10 weight percent upon full hydration, and

wherein said ophthalmic lens has an oxygen transmissibility of at least about 70 barrers/mm and an ion permeability characterized either by (a) an Ionoton Ion Permeability Coefficient of greater than about 0.2×10^{-6} cm²/sec, or (2) an Ionoflux Diffusion Coefficient of greater than about 1.5×10^{-6} mm²/min, wherein said ion permeability is measured with respect to sodium ions.

50. An ophthalmic lens comprising a core material surrounded, at least in part, by a surface modified by a surface treatment process, said lens having ophthalmically compatible inner and outer surfaces which are more hydrophilic and lipophobic than the core material, said lens being suited to extended periods of wear in continuous, intimate contact with ocular tissue and ocular fluids while having adequate movement on the eye with blinking to promote adequate tear exchange and without producing significant corneal swelling, without having substantial amounts of lipid adsorption, and without causing substantial wearer discomfort during a period of wear of at least 4 days, said lens comprising a polymeric material which has a high oxygen permeability equal to or greater than about 69 barrers and a high ion permeability, said polymeric material being formed from polymerizable materials polymerized in an atmosphere substantially free of oxygen comprising:

- (a) at least one oxyperm polymerizable material and
- (b) at least one ionoperm polymerizable material,

wherein said lens allows oxygen permeation in an amount sufficient to maintain corneal health and wearer comfort during the period of extended, continuous contact with ocular tissue and ocular fluids,

wherein said oxyperm polymerizable material forms a phase or phases substantially separate from the phase or phases formed by said ionoperm polymerizable material,

wherein said lens allows ion or water permeation via ion or water pathways in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable

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during the period of extended, continuous contact with ocular tissue and ocular fluids,

wherein said ionoperm polymerizable material, if polymerized alone would form a hydrophilic polymer having a water content of at least 10 weight percent upon full hydration, and

wherein said ophthalmic lens has an oxygen transmissibility of at least about 70 barrers/mm and an ion permeability characterized either by (1) an Ionoton Ion Permeability Coefficient of greater than about 0.2×10^{-6} cm²/sec or (2) an Ionoflux Diffusion Coefficient of greater than about 1.5×10^{-6} mm²/min, wherein said ion permeability is measured with respect to sodium ions.

51. An ophthalmic lens comprising a core material surrounded, at least in part, by a surface modified by a surface treatment process, said lens having ophthalmically compatible inner and outer surfaces which are more hydrophilic and lipophobic than the core material, said lens being suited to extended periods of wear in continuous, intimate contact with ocular tissue and ocular fluids with adequate movement on the eye with blinking to promote adequate tear exchange and without producing significant corneal swelling, without having substantial amounts of lipid adsorption, and without causing substantial wearer discomfort during a period of wear of at least 4 days, said lens comprising a polymeric material which has a high oxygen permeability of equal to or greater than about 72 barrers and a high ion permeability, said polymeric material being formed from polymerizable materials comprising:

- (a) at least one oxyperm polymerizable material and
- (b) at least one ionoperm polymerizable material,

wherein said lens allows oxygen permeation in an amount sufficient to maintain corneal health and wearer comfort during the period of extended, continuous contact with ocular tissue and ocular fluids,

wherein said oxyperm polymerizable material forms a phase or phases substantially separate from the phase or phases formed by said ionoperm polymerizable material,

wherein said lens allows ion or water permeation via ion or water pathways in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during the period of extended, continuous contact with ocular tissue and ocular fluids,

wherein said ionoperm polymerizable material, if polymerized alone would form a hydrophilic polymer having a water content of at least 10 weight percent upon full hydration, and

wherein said ophthalmic lens has an oxygen transmissibility of at least about 70 barrers/mm and an ion permeability characterized either by (1) an Ionoton Ion Permeability Coefficient of greater than about 0.2×10^{-6} cm²/sec or (2) an Ionoflux Diffusion Coefficient of greater than about 1.5×10^{-6} mm²/min, wherein said ion permeability is measured with respect to sodium ions.

52. An ophthalmic lens having a surface modified by a surface treatment process, said lens having ophthalmically compatible inner and outer surfaces, said lens being suited to extended periods of wear in continuous, intimate contact with ocular tissue and ocular fluids without strong adherence to the ocular tissue to inhibit adequate movement on the eye with blinking to promote adequate tear exchange, without producing significant corneal swelling, without having substantial amounts of lipid adsorption, and without causing substantial wearer discomfort during a period of

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wear of at least 24 hours, said lens comprising a polymeric material which has a high oxygen permeability equal to or greater than about 69 barrers and a high ion permeability, said polymeric material being formed from polymerizable materials comprising:

- (a) at least one oxyperm polymerizable material and
- (b) at least one ionoperm polymerizable material,

wherein said lens allows oxygen permeation in an amount sufficient to maintain corneal health and wearer comfort during the period of extended, continuous contact with ocular tissue and ocular fluids,

wherein said oxyperm polymerizable material forms a phase or phases substantially separate from the phase or phases formed by said ionoperm polymerizable material,

wherein said lens allows ion or water permeation via ion or water pathways in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during the period of extended, continuous contact with ocular tissue and ocular fluids,

wherein said ionoperm polymerizable material, if polymerized alone would form a hydrophilic polymer having a water content of at least 10 weight percent upon full hydration, and

wherein said ophthalmic lens has an oxygen transmissibility of at least about 70 barrers/mm and an ion permeability characterized by an Ionon Ion Permeability Coefficient of greater than about 8.0×10^{-6} cm²/sec, wherein said ion permeability is measured with respect to sodium ions.

53. An ophthalmic lens having a surface modified by a surface treatment process, said lens having ophthalmically compatible inner and outer surfaces, said lens being suited to extended periods of wear in continuous, intimate contact with ocular tissue and ocular fluids with adequate movement on the eye with blinking to promote adequate tear exchange and without producing significant corneal swelling, without having substantial amounts of lipid adsorption, and without causing substantial wearer discomfort during a period of wear of at least 7 days, said lens comprising a polymeric material which has a high oxygen permeability equal to or greater than about 72 barrers and a high ion permeability, said polymeric material being formed from polymerizable materials comprising:

- (a) at least one oxyperm polymerizable material and
- (b) at least one ionoperm polymerizable material,

wherein said lens allows oxygen permeation in an amount sufficient to maintain corneal health and wearer comfort during the period of extended, continuous contact with ocular tissue and ocular fluids,

wherein said oxyperm polymerizable material forms a phase or phases substantially separate from the phase or phases formed by said ionoperm polymerizable material,

wherein said lens allows ion or water permeation via ion or water pathways in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during the period of extended, continuous contact with ocular tissue and ocular fluids,

wherein said ionoperm polymerizable material, if polymerized alone would form a hydrophilic polymer having a water content of at least 10 weight percent upon full hydration,

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wherein said ophthalmic lens has an oxygen transmissibility of at least about 70 barrers/mm and an ion permeability characterized by an Ionon Ion Permeability Coefficient of greater than about 250.0×10^{-6} cm²/sec, wherein said ion permeability is measured with respect to sodium ions, and

wherein said lens has a visible light transmission of at least 80% without any significant undesirable image distortion.

54. An ophthalmic lens comprising a core material surrounded, at least in part, by a surface modified by a surface treatment process, said lens having ophthalmically compatible inner and outer surfaces which are more hydrophilic and lipophobic than the core material, said lens being suited to extended periods of wear in continuous, intimate contact with ocular tissue and ocular fluids without strong adherence to the ocular tissue to inhibit adequate movement on the eye with blinking to promote adequate tear exchange, without producing significant corneal swelling, without having substantial amounts of lipid adsorption, and without causing substantial wearer discomfort during a period of wear of at least 30 days, said lens comprising a polymeric material which has a high oxygen permeability and a high ion permeability, said polymeric material being formed from polymerizable materials comprising:

- (a) at least one oxyperm polymerizable material and
- (b) at least one ionoperm polymerizable material,

wherein said lens allows oxygen permeation in an amount sufficient to maintain corneal health and wearer comfort during the period of extended, continuous contact with ocular tissue and ocular fluids,

wherein said oxyperm polymerizable material forms a phase or phases substantially separate from the phase or phases formed by said ionoperm polymerizable material,

wherein said lens allows ion or water permeation via ion or water pathways in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during the period of extended, continuous contact with ocular tissue and ocular fluids,

wherein said ionoperm polymerizable material, if polymerized alone would form a hydrophilic polymer having a water content of at least 10 weight percent upon full hydration, and

wherein said ophthalmic lens has an oxygen transmissibility of at least about 70 barrers/mm and an ion permeability characterized by an Ionon Ion Permeability Coefficient of greater than about 350.0×10^{-6} cm²/sec wherein said ion permeability is measured with respect to sodium ions.

55. An ophthalmic lens comprising a core material surrounded, at least in part, by a surface modified by a plasma surface treatment process, said lens having ophthalmically compatible inner and outer surfaces having greater surface hydrophilicity than the core material of said lens, said lens being suited to extended periods of wear in continuous, intimate contact with ocular tissue and ocular fluids with adequate movement on the eye with blinking to promote adequate tear exchange and without producing significant corneal swelling, without having substantial amounts of lipid adsorption, and without causing substantial wearer discomfort during a period of wear of at least 24 hours, said lens comprising a polymeric material which has a high oxygen permeability and a high ion permeability, said polymeric material being formed from polymerizable materials comprising:

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(a) at least one oxyporm polymerizable material and
 (b) at least one ionoporm polymerizable material,
 wherein said lens allows oxygen permeation in an amount
 sufficient to maintain corneal health and wearer comfort
 during the period of extended, continuous contact
 with ocular tissue and ocular fluids,

wherein said oxyporm polymerizable material forms a
 phase or phases substantially separate from the phase
 or phases formed by said ionoporm polymerizable
 material,

wherein said lens allows ion or water permeation via ion
 or water pathways in an amount sufficient to enable the
 lens to move on the eye such that corneal health is not
 substantially harmed and wearer comfort is acceptable
 during the period of extended, continuous contact with
 ocular tissue and ocular fluids,

wherein said ionoporm polymerizable material, if poly-
 merized alone would form a hydrophilic polymer hav-
 ing a water content of at least 10 weight percent upon
 full hydration, and

wherein said ophthalmic lens has an oxygen transmissi-
 bility of at least about 70 barrers/mm and an ion
 permeability characterized by an Ionoflux Diffusion
 Coefficient of greater than about 6.4×10^{-6} mm²/min,
 wherein said ion permeability is measured with respect
 to sodium ions.

56. An ophthalmic lens having ophthalmically compatible
 inner and outer surfaces, said lens being suited to extended
 periods of wear in continuous, intimate contact with ocular
 tissue and ocular fluids with adequate movement on the eye
 with blinking to promote adequate tear exchange and with-
 out producing significant corneal swelling, without having
 substantial amounts of lipid adsorption, and without causing
 substantial wearer discomfort during a period of wear of at
 least 24 hours, said lens comprising a polymeric material
 which has a high oxygen permeability and a high ion
 permeability, said polymeric material being formed from
 polymerizable materials comprising:

(a) at least one oxyporm polymerizable material and
 (b) at least one ionoporm polymerizable material,

wherein said lens allows oxygen permeation in an amount
 sufficient to maintain corneal health and wearer comfort
 during the period of extended, continuous contact
 with ocular tissue and ocular fluids,

wherein said oxyporm polymerizable material forms a
 phase or phases substantially separate from the phase
 or phases formed by said ionoporm polymerizable
 material,

wherein said lens allows ion or water permeation via ion
 or water pathways in an amount sufficient to enable the
 lens to move on the eye such that corneal health is not
 substantially harmed and wearer comfort is acceptable
 during the period of extended, continuous contact with
 ocular tissue and ocular fluids,

wherein said ionoporm polymerizable material, if poly-
 merized alone would form a hydrophilic polymer hav-
 ing a water content of at least 10 weight percent upon
 full hydration,

wherein said ophthalmic lens has an oxygen transmissi-
 bility of at least about 70 barrers/mm and an ion
 permeability characterized by an Ionoflux Diffusion
 Coefficient of greater than about 2.6×10^{-6} mm²/min,
 wherein said ion permeability is measured with respect
 to sodium ions, and

wherein said lens is autoclaved without lowering either
 said oxygen permeability or said ion permeability

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below levels sufficient to maintain good corneal health
 and on-eye movement.

57. An ophthalmic lens comprising a core material
 surrounded, at least in part, by a surface modified by a
 plasma surface treatment process, said lens having oph-
 thalmically compatible inner and outer surfaces having
 greater surface hydrophilicity than the core material of said
 lens, said lens being plasma surface treated in the presence
 of (a) a C₁₋₆ alkane and (b) a gas selected from the group
 consisting of nitrogen, argon, oxygen and mixtures thereof,
 said lens being suited to extended periods of wear in
 continuous, intimate contact with ocular tissue and ocular
 fluids with adequate movement on the eye with blinking to
 promote adequate tear exchange and without producing
 significant corneal swelling, without having substantial
 amounts of lipid adsorption, and without causing substantial
 wearer discomfort during a period of wear of at least 24
 hours, said lens comprising a polymeric material which has
 a high oxygen permeability and a high ion permeability, said
 polymeric material being formed from polymerizable mate-
 rials comprising:

(a) at least one oxyporm polymerizable material and

(b) at least one ionoporm polymerizable material,

wherein said lens allows oxygen permeation in an amount
 sufficient to maintain corneal health and wearer com-
 fort during the period of extended, continuous contact
 with ocular tissue and ocular fluids,

wherein said oxyporm polymerizable material forms a
 phase or phases substantially separate from the phase
 or phases formed by said ionoporm polymerizable
 material,

wherein said lens allows ion or water permeation via ion
 or water pathways in an amount sufficient to enable the
 lens to move on the eye such that corneal health is not
 substantially harmed and wearer comfort is acceptable
 during the period of extended, continuous contact with
 ocular tissue and ocular fluids,

wherein said ionoporm polymerizable material, if poly-
 merized alone would form a hydrophilic polymer hav-
 ing a water content of at least 10 weight percent upon
 full hydration, and

wherein said ophthalmic lens has an oxygen transmissi-
 bility of at least about 70 barrers/mm and an ion
 permeability characterized by an Ionoflux Diffusion
 Coefficient of greater than about 6.4×10^{-6} mm²/min,
 wherein said ion permeability is measured with respect
 to sodium ions.

58. An ophthalmic lens of claims 49, 50, 51, 52, 53, 54,
 55 or 57, wherein said lens is produced by a manufacturing
 method without lowering either said oxygen permeability or
 said ion permeability below levels sufficient to maintain
 good corneal health and on-eye movement.

59. An ophthalmic lens having a surface modified by a
 surface treatment process, said lens having ophthalmically
 compatible inner and outer surfaces, said lens being suited
 to extended periods of wear in continuous, intimate contact
 with ocular tissue and ocular fluids with adequate movement
 on the eye with blinking to promote adequate tear exchange
 and without producing significant corneal swelling, without
 having substantial amounts of lipid adsorption, and without
 causing substantial wearer discomfort during a period of
 wear of at least 24 hours, said lens comprising a polymeric
 material which has a high oxygen permeability and a high
 ion permeability, said polymeric material being formed from
 polymerizable materials comprising at least one polymeriz-
 able material comprising:

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(a) at least one oxyperm segment; and

(b) at least one ionoperm segment,

wherein said lens allows oxygen permeation in an amount sufficient to maintain corneal health and wearer comfort during the period of extended, continuous contact with ocular tissue and ocular fluids,

wherein said oxyperm segment forms a phase or phases substantially separate from the phase or phases formed by said ionoperm segment,

wherein said lens allows ion or water permeation via ion or water pathways in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during the period of extended, continuous contact with ocular tissue and ocular fluids,

wherein said ionoperm segment, if polymerized alone, would form a hydrophilic polymer having a water content of at least 10 weight percent upon full hydration,

wherein said ophthalmic lens has an oxygen transmissibility of at least about 70 barrers/mm and an ion permeability characterized by an Ionoton Ion Permeability Coefficient of greater than about $8.0 \times 10^{-6} \text{ cm}^2/\text{sec}$, wherein said ion permeability is measured with respect to sodium ions, and

wherein said lens does not have any significant undesirable image distortion.

60. An ophthalmic lens having ophthalmically compatible inner and outer surfaces, said lens being suited to extended periods of wear in continuous, intimate contact with ocular tissue and ocular fluids with adequate movement on the eye with blinking to promote adequate tear exchange and without producing significant corneal swelling, without having substantial amounts of lipid adsorption, and without causing substantial wearer discomfort during a period of wear of at least 24 hours, said lens comprising a polymeric material which has a high oxygen permeability and a high ion permeability, said polymeric material being formed from polymerizable materials comprising at least one polymerizable material comprising:

(a) at least one oxyperm segment; and

(b) at least one ionoperm segment,

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wherein said lens allows oxygen permeation in an amount sufficient to maintain corneal health and wearer comfort during the period of extended, continuous contact with ocular tissue and ocular fluids,

wherein said oxyperm segment forms a phase or phases substantially separate from the phase or phases formed by said ionoperm segment,

wherein said lens allows ion or water permeation via ion or water pathways in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during the period of extended, continuous contact with ocular tissue and ocular fluids,

wherein said ionoperm segment, if polymerized alone would form a hydrophilic polymer having a water content of at least 10 weight percent upon full hydration,

wherein said ophthalmic lens has an oxygen transmissibility of at least about 70 barrers/mm and an ion permeability characterized by an Ionoflux Ion Permeability Coefficient of greater than about $6.4 \times 10^{-6} \text{ mm}^2/\text{min}$, wherein said ion permeability is measured with respect to sodium ions, and

wherein said lens is autoclaved without lowering either said oxygen permeability or said ion permeability below levels sufficient to maintain good corneal health and on-eye movement.

61. An ophthalmic lens of claims 49, 50, 51, 52, 59 or 60, wherein said ophthalmic lens has an oxygen transmissibility of at least about 75 barrers/mm.

62. An ophthalmic lens of claims 49, 50, 51, 52, 59 or 60, wherein said ophthalmic lens has an oxygen transmissibility of at least about 87 barrers/mm.

63. An ophthalmic lens of claims 49, 50, 51, 52, 53, 54, 55, 57, or 59 wherein said lens is autoclaved without lowering either said oxygen permeability or said ion permeability below levels sufficient to maintain good corneal health and on-eye movement.

64. An ophthalmic lens of claim 49, 50, 51, 52, or 59 wherein said surface treatment process is a plasma surface treatment process and said period of extended wear is at least 7 days.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

5,760,100

Page 1 of 4

PATENT NO. :

DATED : June 2, 1998

INVENTOR(S) :

Nicolson, et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Col. 11, ln. 43 reads "6.4x10⁶" and should read ~~6.4x10⁶~~

Col. 69, ln. 26 reads "lens having ophthalmically compatible" and should read ~~lens having ophthalmically compatible~~

Col. 69, ln. 39 reads "wherein said oxypem polymerizablea" and should read ~~wherein said oxypem polymerizable~~

Col. 69, ln. 40 reads "phases substantially seperate" and should read ~~phases substantially separate~~

Col. 69, ln. 46 reads "substantially hared" and should read ~~substantially harmed~~

Col. 69, ln. 49 reads "wherein said ionopem polyrnerizable" and should read ~~wherein said ionopem polymerizable~~

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

5,760,100

Page 2 of 4

PATENT NO. :

DATED : June 2, 1998

INVENTOR(S) :

Nicolson, et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Col. 69, ln. 51 reads "a water content of atleast" and should read --a water content of at least--

Col. 69, ln. 55 reads "permeability characteized" and should read --permeability characterized--

Col. 69, ln. 58 reads "greater than about $1.5 \times 10^{31.6}$ " and should read --greater than about 1.5×10^6 --

Col. 70, ln. 57 reads "ability Coefficeint" and should read --ability Coefficient--

Col. 70, ln. 59 reads "an lonoflux Diffuision" and should read --an lonoflux Diffusion--

Col. 71, ln. 30 reads "An ophthlamic lens" and should read --An ophthalmic lens--

Col. 71, ln. 32 reads "any clinically significant" and should read "any clinically significant--

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION
5,760,100 Page 3 of 4

PATENT NO. :

DATED : June 2, 1998

INVENTOR(S) :

Nicolson, et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Col. 72, ln. 67 reads "Coefficient of greater than about $0.2 \times 10^{31.6}$ " and should read --Coefficient of greater than about 0.2×10^{-6} --

Col. 73, ln. 2 reads "about $1.5 \times 10^{-6} \text{ mm}^2 \text{ min.}$ " and should read --about $1.5 \times 10^{-6} \text{ mm}^2 \text{ min.}$ --

Col. 73, ln. 3 reads "with respect to sodiumn ions." and should read --with respect to sodium ions.--

Col. 74, lns. 3 and 4 reads "'lon Pemeability Coefficient" and should read --Ion Permeability Coefficient--

Col. 71, ln. 60 reads "lens of claim 26" and should read --lens of claim 36--

Col. 71, ln. 66 reads "lens of claim 26" and should read --lens of claim 36--

Col. 72, ln. 7 reads " $\text{cm}^2 \text{ min.}$ " and should read -- $\text{cm}^2 \text{ sec.}$ --

Col. 72, ln. 9 reads "lens of claim 1" and should read --lens of claim 36--

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

5,760,100

Page 4 of 4

PATENT NO. :

DATED : June 2, 1998

INVENTOR(S) :

Nicolson, et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Col. 72, ln. 31 reads "cm²/min." and should read --cm²/sec.--

Col. 72, ln. 49 reads "said oxyperm polymerizable mateerial forms" and should read --said oxyperm segment forms--

Col. 72, ln. 52-53 reads "said ionoperm polymerizable material." and should read --said ionoperm segment.--

Col. 72, ln. 60 reads "said ionoperm polymerizable material." and should read --said ionoperm segment.--

Signed and Sealed this
Fifteenth Day of June, 1999

Attest:



Q. TODD DICKINSON

Attesting Officer

Acting Commissioner of Patents and Trademarks